

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kevin P. CONNORS et al.

Application No.: 10/789,139

Confirmation No.: 9270

Filed: February 27, 2004

Art Unit: 3769

For: SYSTEM AND METHOD FOR HEATING
SKIN USING LIGHT TO PROVIDE TISSUE
TREATMENT

Examiner: David M. Shay

**SUPPLEMENTAL DECLARATION OF
DR. MACRENE ALEXIADES-ARMENAKAS**

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Macrene Alexiades-Armenakas, declare as follows:

1. This Supplemental Declaration has been prepared in response to the pending Final Office Action. This Supplemental Declaration should be read in conjunction with my previous declaration. Prior to making this Supplemental Declaration, I reviewed the currently pending Final Office Action and once again reviewed the prior art references discussed below.

2. In my previous Declaration, I rendered the opinion that the prior art of record did not teach or suggest a method for skin tightening that utilized a broadband spectrum of radiation principally between 1050nm and 1850nm. Further, I rendered the opinion that the prior art of record did not teach a method for skin tightening wherein the treatment time of the broadband radiation was between 1.2 and 5 seconds.

3. Pages 2 to 4 of the Final Office Action contain the responses of the Examiner to my previous Declaration. In this section of the Final Office Action, the

Examiner specifically addressed the teachings in Anderson (U.S. 6,120,497) and Altshuler (2004/0093042).

4. As noted in my previous Declaration, Anderson relates to a method of treating skin wrinkles. His primary teaching relates to tissue treatment with a single wavelength generated by a laser system. Anderson also teaches that the light source could generate “incoherent radiation.” Anderson never mentions treatment with *broadband* radiation but repeatedly refers to the treatment radiation as “a” wavelength or “the” wavelength. I opined that taken as a whole, Anderson does not teach a treatment method using broadband light as required by pending independent claim 15.

5. In response, the Examiner stated that Anderson’s teaching of an incoherent source would lead one of ordinary skill in the art to believe that the use of a wavelength “band,” rather than a single wavelength, would provide useful results. From a physics standpoint, it would be expected that a filtered, incoherent light source would generate a “wavelength band” that would have a bandwidth larger than the very narrow bandwidth generated by the types of solid state lasers discussed in the Anderson patent. If the Examiner merely intended to refer to a narrow wavelength “band” as opposed to a single wavelength generated by a laser, then the Examiner presumably agrees that Anderson fails to teach a treatment method using **broadband** light. However, if the Examiner intended to suggest that Anderson in any way teaches a treatment method with broadband light as recited in claim 15 then I strongly disagree.

6. As noted above, nowhere does Anderson expressly suggest treatment with broadband light. More importantly, Anderson repeatedly states that his method relates to treatment narrowband light.

(a) Abstract: “The beam of radiation has a wavelength of between 1.3 and 1.8 microns.”

(b) Column 2, line 67: “The method comprises generating a beam of radiation having a wavelength between 1.3 and 1.8 microns.”

(c) Column 3, line 31: “The radiation source generates a beam of radiation having a wavelength between 1.3 and 1.8 microns.”

(e) Column 4, line 24: “In particular, the wavelength of the radiation beam has been chosen to maximize absorption in the targeted region of the dermis, and the fluence or power density, depending on the type of radiation, has been chosen to minimize erythema. The wavelength range chosen has a tissue absorption coefficient preferably in the range of about 1 to 20 cm^{-1} . Thus, the beam preferably has a wavelength of between about 1.3 and 1.8 microns in one embodiment. Within this wavelength range, radiation energy applied through the surface of the skin is deposited predominantly in the dermal region of the skin. In one embodiment, the radiation beam has a nominal wavelength of approximately 1.5 microns.”

(f) Column 6, line 1: “The penetration depth can be approximated by taking the reciprocal of the absorption coefficient of the skin at the wavelength of the radiation.”

7. In addition, both of the independent claims in the Anderson patent describe generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns. If Anderson intended to teach a treatment method that utilized broadband radiation, he would not have written his claims to refer to a beam having “a” wavelength. In view of the above, in my opinion, Anderson cannot be properly relied upon for teaching a treatment method using broadband radiation.

8. In the Office Action, The Examiner has also argued that Anderson teaches certain treatment times. The Examiner reaches this conclusion by pointing out that Anderson teaches the application of 10 to 150 joules of energy using 5 to 100 watts of power. The Examiner calculates that it would require between 2 seconds and 40 seconds to deliver this range of power with the specified energy levels.

9. In making the above analysis, the Examiner misreads Anderson. More specifically, at column 4, line 42, Anderson says that the laser radiation has a fluence of 10 to 150 joules, not an energy of 10 to 150 joules. One skilled in the art would understand that fluence relates to the energy applied over a given area (typically per cm^2). One cannot calculate a treatment time given only fluence and power. Accordingly, Anderson fails to teach the treatment times recited in pending claim 15.

10. Turning now to the Altshuler publication, in my previous Declaration, I attempted to explain why the various wavelength ranges set forth in Anderson would be insufficient to render obvious the claimed method for skin tightening using a wavelength range of 1050nm to 1850nm. In response, the Examiner pointed out that the 1100nm to 1250nm range disclosed by Anderson falls within the scope of the claimed range. Further, the Examiner questioned why treating with shorter wavelengths, i.e., below 1050nm, would be detrimental.

11. Before addressing the specific issues raised by the Examiner, I will first address a fundamental weakness of the overall teachings in Altshuler. As one skilled in the art, I view the disclosure of Altshuler as a large catalogue of possible treatment concepts with a relatively small amount of concrete teachings that would be necessary to effectively carry out specific procedures. Starting with paragraphs 28, 29, and 30, Altshuler provides a laundry list of targets for light treatment including (a) cellulite and subcutaneous fat treatment, (b) physical therapy, (c) muscle and skeletal treatments, (d) treatment of spinal cord problems, (e) treatment of cumulative trauma disorders (CTD's), (f) cancer therapy, (g) treatments of cortical bone, synovium joint capsules, tendon sheaths, menisci, myofascial interfaces, periosteum, fibrotic muscle, or major nerve trunk, and (h) reshaping procedures such as non-invasive wrinkle removal through stimulation of collagen production in a subsurface region of tissue. Altshuler also teaches many different possible wavelength ranges, including (at paragraph 10) 600nm to 1850nm; 800nm to 1350nm, 1050nm to 1250nm, and (at paragraph 93) 800nm to 1800nm; 900nm to 1400nm and 1100nm to 1250nm. Table 1 of Altshuler includes still further wavelength ranges including maximum, preferable, and most preferable ranges.

12. None of the specified ranges correspond to the claimed range of 1050nm to 1850nm. None of the specified ranges is tied to skin tightening. There is no rationale disclosed in Altshuler that would allow one skilled in the art to determine the optimum wavelength range for skin tightening. One skilled in the art would simply not find the claimed range of 1050nm to 1850nm for skin tightening to be taught or suggested based on Altshuler's scattershot disclosure.

13. In the Final Office Action, the Examiner questioned how including shorter wavelength radiation in the treatment radiation, i.e., below 1050nm, would “negate the efficacy” of the upper ranges of the applied wavelengths. The reason these shorter wavelengths would negate the efficacy of the longer wavelengths is that the shorter wavelengths are highly absorbed in the melanosomes and hemoglobin located in the upper layers of the skin. This will result in a high level of absorption of these shorter wavelengths in these superficial targets generating heat in the superficial layers including the epidermis, dermo-epidermal junction, and the papillary blood vessels, greatly limiting the ability to deliver higher fluences to the lower depths and larger targets required for a skin tightening procedure. Based on my experience, the wavelength ranges suggested by Altshuler that include the 800nm to 1050nm range or the 900nm to 1050nm range will not work well because either (a) not enough fluence will be delivered to the lower depths or (b) assuming the power were increased to obtain the necessary fluence to treat the tissue at the lower depths, the upper levels of the patient’s skin, e.g., epidermis, dermo-epidermal junction, and papillary blood vessels, would be heated too much, causing pain, potential burns, and potential vascular necrosis.

14. It is also my opinion, based on my experience, that treatment with a very narrow band, such as the 1100nm to 1250nm range suggested by Altshuler, will not work for skin tightening. This narrow wavelength band has high absorption in the sebaceous glands, making it extremely difficult to deliver enough energy to the collagen and other dermal targets necessary to obtain the desired result. In my opinion, in order to obtain satisfactory results, the treatment radiation should include a broad-band of wavelengths, including those above 1250nm and preferably up to about 1850nm.

15. Based on the above, it is my opinion that the teachings in Altshuler would not render obvious a method of skin tightening that includes treating the tissue with a wavelength band of 1050nm to 1850nm.

16. In the Office Action at page 6, the Examiner repeated his reliance on Altshuler’s specified treatment times of 2 seconds to 2 hours, noting that selecting a treatment time to obtain the desired temperature rise would be obvious to one skilled in the art. In my previous Declaration at paragraph 13, I disputed this argument since

appropriate treatment times are generally difficult to determine. Further, the claimed treatment time of 1.2 to 5 seconds was selected to induce neocollagenesis and neoeelastogenesis. I opined that this claimed treatment time would not be obvious from Altshuler's teaching of 2 seconds to 2 hours. The Examiner's response to my comments in paragraph 13 of my Declaration was to instead rely on the supposed time interval disclosed in Anderson. As already discussed above, the Examiner's view of the teachings of Anderson on a treatment interval is not correct.

17. The Examiner should also note that it is not so easy to accurately determine tissue temperatures in layers below the surface of the skin. In the past, those temperatures were most often calculated based on surface temperature measurements using Monte Carlo-type heat flow analyses and temperature estimates. Alternatively, thermocouple probes can now be inserted under the skin in an attempt to measure the real time temperature rise in deeper tissue. Since determining the proper treatment interval is not trivial and the bulk of Altshuler's suggested treatment time is far longer than would be appropriate (up to two hours), it is my opinion that the treatment time interval recited in claim 15 is not obvious in view of Altshuler.

Application No. 10/789,139
Supp. Alexiades Decl.

7

Docket No.: 658312 001000

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements are like so made are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: _____

11/10/10


Macrene Alexiades Armenakas